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March 9, 2004

OVERNIGHT COURIER 3/9/04

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

This petition is submitted in quadruplicate under Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act, and in accordance with 21 CFR 10.30, on behalf of a client requesting the Commissioner of the Food and Drug Administration to declare that the drug product Glimepiride Tablets, 3 mg and 6 mg, are suitable for submission in an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration make a determination that Glimepiride Tablets, 3 mg and 6 mg, are suitable for submission in an ANDA. The reference-listed drug product upon which this petition is based is Amaryl® (glimepiride) Tablets, 1 mg, which appears in the 24th edition of the Electronic Orange Book (see Attachment 1). The listed drug product is also approved in strengths of 2 mg and 4 mg. Additionally, a petition submitted June 19, 2003 for a new, higher strength of 8 mg was approved on October 6, 2003 [(Docket No. 03P-0283/CP1) see petition approval letter Attachment 2]. Therefore, the petitioner seeks a change in strength (from 1 mg, 2 mg and 4 mg tablets to include 3 mg tablets, an intermediate strength, and 6 mg tablets, a new, higher strength) from that of the listed drugs.

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in strength from a listed drug provided the FDA has approved a petition that proposed the filing of such an application. Amaryl® (glimepiride) Tablets, the reference-listed drug upon which this petition is based, are available in tablet dosage form and available in differing strengths containing 1 mg, 2 mg and 4 mg of glimepiride. Additionally, the petition submitted June 19, 2003 for a new, higher strength of 8 mg was approved on October 6, 2003 (Docket No. 03P-0283/CP1). The proposed drug products represent the same dosage form and route of administration, differing only in strength from the reference listed drug.

As is stated in the approved labeling for the RLD, there is no fixed dosage regimen for the management of diabetes mellitus with Amaryl® (glimepiride) or any other hypoglycemic agent, it is clear that each patient must be titrated to an effective dose of the drug product specific to the individual patient's needs and response to the medication. The usual maintenance dose is 1 mg to 4 mg once daily. The maximum recommended dose is 8 mg once daily. After reaching a dose of 2 mg, the labeling of the RLD indicates that dosage increases should be made in increments of no more than 2 mg at 1- to 2-week intervals based upon the patient's blood glucose response. The

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availability of the proposed 3 mg and 6 mg tablet strengths will provide a more convenient single-tablet dose for patients who, based on their individual requirements, must now take multiple tablets to attain their prescribed dose. It will also provide prescribing physicians a greater degree of flexibility in selecting proper individualized maintenance doses for specific patients needs.

There should be no question of safety or efficacy raised regarding the requested new drug product as the uses, dose, dosage form and route of administration of the proposed drug product are the same as that of the listed drug product. The approved labeling of the reference-listed drug (Attachment 3) indicates that the maximum recommended dose for Amaryl® (glimepiride) Tablets is 8 mg once daily. The proposed strengths of 3 mg and 6 mg represent intermediate strengths below the maximum recommended dose. Labeling of the proposed product (Attachment 4) will be the same as the approved labeling of the reference-listed drug product with exception to the introduction of the 3 mg and 6 mg strengths in the "Description" and "How Supplied" sections.

C. Environmental Impact

An environmental assessment on the action requested in this petition qualifies for a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30 (b), economic impact information is to be submitted only when requested by the Commissioner. We will gladly provide such information, if so requested.

E. Certification

The undersigned certifies that to the best of its knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which is unfavorable to the petition.

Respectfully submitted:

Robert Pollock PK

Robert W. Pollock
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Attachments:

1. 24th Edition of the Orange Book
2. Petition Approval Letter, dated October 6, 2003
3. Approved Labeling
4. Labeling of the Proposed Product

cc: Emily Thomas, Office of Generic Drugs

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